Appl. No. 09/688,672 Amdt. dated June 14, 2005 Amendment under 37 CFR 1.116 Expedited Procedure Examining Group 1645

### <u>REMARKS</u>

#### I. Status of the Claims

Claims 1-115 were originally filed. Claims 9, 10, 28-104, and 110 have been canceled. Claims 1-8, 11-27, 105-109, and 111-115 are currently under examination. Applicants note with appreciation that the Examiner has indicated the allowability of claims 1-4, 7, 8, 11-18, 20-27, 105-109, and 111-115.

## II. Claim Rejections

# A. Obviousness-Type of Double Patenting

The Examiner maintained the rejection of claims 5 and 19 under the judicially created doctrine of obviousness-type of double patenting, alleging that these two claims are unpatentable over claims 1-3 of U.S. Patent No. 6,592,877 ("the '877 patent"). Applicants respectfully traverse the rejection.

The subject matter of claims 1-3 of the '877 patent is an isolated fusion protein comprising four *M. tuberculosis* antigens: TbRa3 (SEQ ID NO:77), Tb38-1 (SEQ ID NO:88), TbH4 (SEQ ID NO:89), and 38kD (SEQ ID NO:155). In contrast, claim 5 of the present application is directed to a composition that contains a fusion protein comprising *M. tuberculosis* antigens MTb81 and Mo2, whereas claim 19 are directed to a composition that contains a fusion protein comprising at least two of *M. tuberculosis* antigens MTb81, Mo2, TbRa3, 38kD, Tb38-1 (MTb11), FL TbH4, HTCC#1 (Mtb40), TbH9, MTCC#2 (Mtb41), DPEP, DPPD, TbRa35, TbRa12, MTb59, MTb82, Erd14 (Mtb16), FL TbRa35 (Mtb32A), DPV (Mtb8.4), MSL (Mtb9.8), MTI (Mtb9.9A, also known as MTI-A), ESAT-6, α-crystalline, and 85 complex.

Because claim 5 relates to a fusion protein that comprises two *M. tuberculosis* antigens different from the four antigens named in claims 1-3 of the '877 patent, Applicants do not believe claim 5 is obvious in view of claims 1-3 of the '877 patent. Although at first glance claim 19 appears to refer to all four *M. tuberculosis* antigens named in claims 1-3 of the '877 patent, claim 19 in fact names an antigen *FL TbH4* instead of TbH4 (SEQ ID NO:89) in the

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claims of the '877 patent. A close inspection of the actual amino acid sequences of FL TbH4 of the present application (which is SEQ ID NO:12, according to description on page 6 line 3 of the specification) and TbH4 of the '877 patent (which is SEQ ID NO:89) reveals that the two sequences are significantly different: SEQ ID NO:12 of the present application is a peptide of 286 amino acids and SEQ ID NO:89 of the '877 patent is a peptide of 166 amino acids (see Exhibit I). It is therefore clear that the fusion protein relevant to claim 19 is defined by a combination of *M. tuberculosis* antigens, not all of which are named in claims 1-3 of the '877 patent. Further, claim 19 does not explicitly name all four antigens recited in claims 1-3 of the '877 patent. Applicants therefore contend that the fusion protein of claim 19 is not obvious over claims 1-3 of the '877 patent.

As such, the withdrawal of the obviousness-type double patenting rejection is respectfully requested.

## B. 35 U.S.C. §112, Second Paragraph

The Examiner rejected claim 6 under 35 U.S.C. §112, second paragraph, for its dependency from a rejected base claim. As discussed above, the only other outstanding rejection, the obviousness-type double patenting rejection, has been properly addressed. The rejection of claim 6 is therefore obviated.

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# **CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

Chuan Gao

Reg. No. 54,111

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Attachments (Exhibit I: SEQ ID NO:89 of U.S. Patent No. 6,592,877 and SEQ ID NO:12 of the

present application)

CG:cg 60489108 v1

#### -continued

Ser Gly Asp Leu Lys Thr Gln Ile Asp Gln Val Glu Ser Thr Ala Gly Ser Leu Gln Gly Gln Trp Arg Gly Ala Ala Gly Thr Ala Ala Gln Ala 35 40 45Ala Val Val Arg Phe Gln Glu Ala Ala Asn Lys Gln Lys Gln Glu Leu Asp Glu Ile Ser Thr Asm Ile Arg Glm Ala Gly Val Glm Tyr Ser Arg 65 70 75 80 Ala Asp Glu Glu Gln Gln Ala Leu Ser Ser Gln Met Gly Phe  $85 \\ \hspace*{1.5cm} 90 \\ \hspace*{1.5cm} 95 \\ \hspace*{1.5cm}$ 

#### (2) INFORMATION FOR SEQ ID NO:89:

- (i) SEQUENCE CHARACTERISTICS:
  - (A) LENGTH: 166 amino acids
  - (B) TYPE: amino acid
  - (C) STRANDEDNESS: single
  - (D) TOPOLOGY: linear
- (xi) SEQUENCE DESCRIPTION: SEQ ID NO:89:

Met Thr Gln Ser Gln Thr Val Thr Val Asp Gln Gln Glu Ile Leu Asn 1  $\phantom{\bigg|}$  5  $\phantom{\bigg|}$  10  $\phantom{\bigg|}$  15

Arg Ala Asn Glu Val Glu Ala Pro Met Ala Asp Pro Pro Thr Asp Val  $20 \ \ 25 \ \ 30$ 

Pro Ile Thr Pro Cys Glu Leu Thr Xaa Xaa Lys Asn Ala Ala Gln Gln 35 40 45

Xaa Val Leu Ser Ala Asp Asn Met Arg Glu Tyr Leu Ala Ala Gly Ala 50 55 60

Lys Glu Arg Gln Arg Leu Ala Thr Ser Leu Arg Asn Ala Ala Lys Xaa 65 70 75 80

Tyr Gly Glu Val Asp Glu Glu Ala Ala Thr Ala Leu Asp Asn Asp Gly 85 90 95

Glu Gly Thr Val Gln Ala Glu Ser Ala Gly Ala Val Gly Gly Asp Ser 100 105 110

Ser Ala Glu Leu Thr Asp Thr Pro Arg Val Ala Thr Ala Gly Glu Pro 115 120 125

Asn Phe Met Asp Leu Lys Glu Ala Ala Arg Lys Leu Glu Thr Gly Asp 130 135 140

Gln Gly Ala Ser Leu Ala His Xaa Gly Asp Gly Trp Asn Thr Xaa Thr 145 150 150 160

#### (2) INFORMATION FOR SEQ ID NO:90:

- (i) SEQUENCE CHARACTERISTICS:
  - (A) LENGTH: 5 amino acids

  - (B) TYPE: amino acid (C) STRANDEDNESS: single (D) TOPOLOGY: linear
- (xi) SEQUENCE DESCRIPTION: SEQ ID NO:90:

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## (2) INFORMATION FOR SEQ ID NO:91:

(i) SEQUENCE CHARACTERISTICS:

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                                 25
Ser Leu Gln Gly Gln Trp Arg Gly Ala Ala Gly Thr Ala Ala Gln Ala
                             40'
Ala Val Val Arg Phe Gln Glu Ala Ala Asn Lys Gln Lys Gln Glu Leu
                         55
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Ala Asp Glu Glu Gln Gln Ala Leu Ser Ser Gln Met Gly Phe
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atgaacggc ggcatcaaat tagtgcagga acctttcagt ttagcgacga taatggctat 180
agcactaagg aggatgatcc gatatgacgc agtcgcagac cgtgacggtg gatcagcaag 240
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<223> Xaa = any amino acid
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Leu Pro Gly Phe Asp Glu Gly Gly Leu Arg Pro Xaa Lys 280

275

<sup>&</sup>lt;210> 13

<sup>&</sup>lt;211> 1200

<sup>&</sup>lt;212> DNA

<sup>&</sup>lt;213> Mycobacterium tuberculosis